The approval process for medical devices often appears to be an obstacle to developing innovative products. But there is another way – an experience report.

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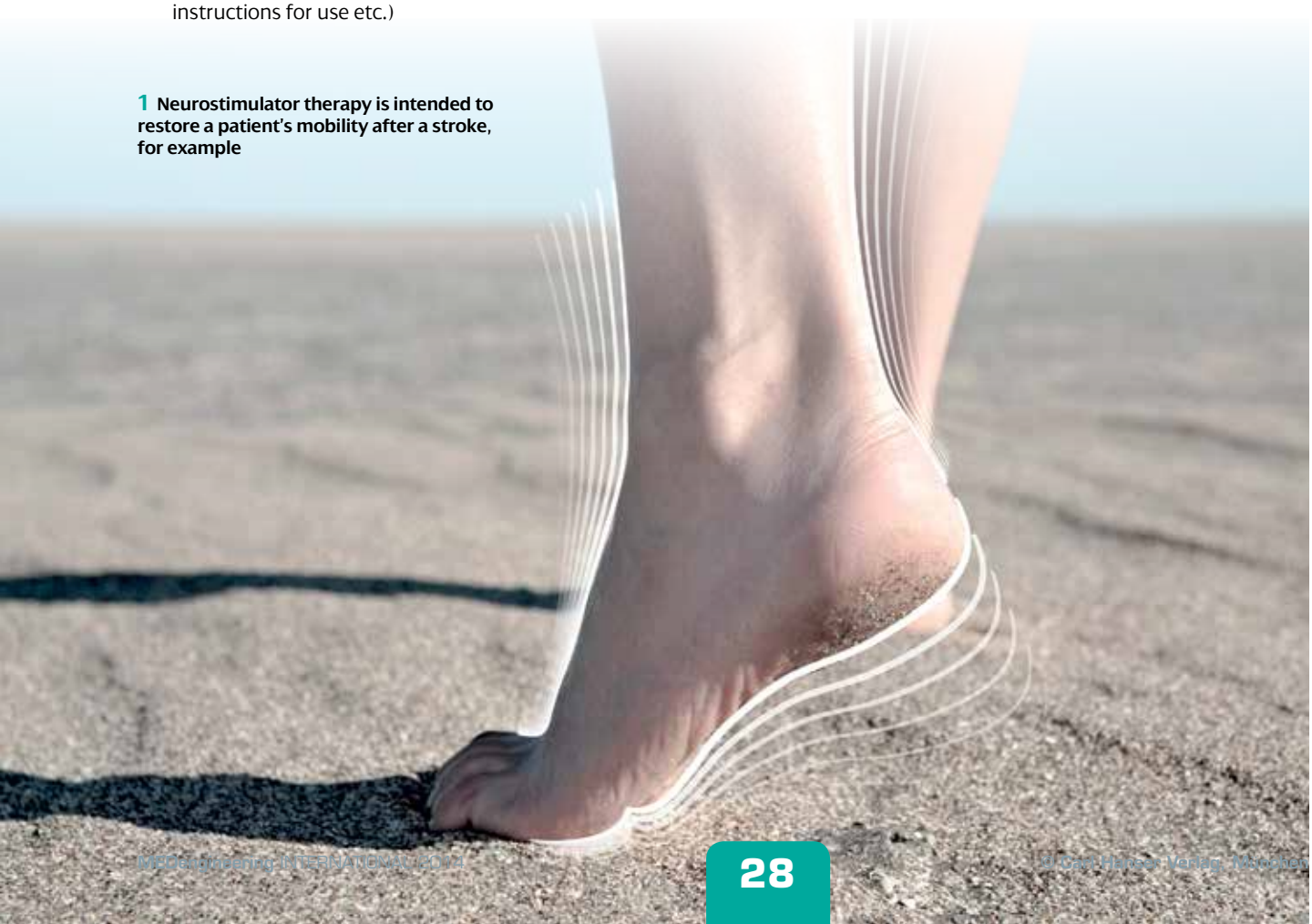
It is a long way from an idea to a finished product, and many issues need to be considered as regards medical technology. For example, technical documentation is required for products in all risk categories (I, IIa, IIb and III). The European Association for Medical Devices of Notified Bodies has summarized the minimum requirements in the Technical Documentation (NB-MED/ 2.5.1/Rec.5 rev.4):

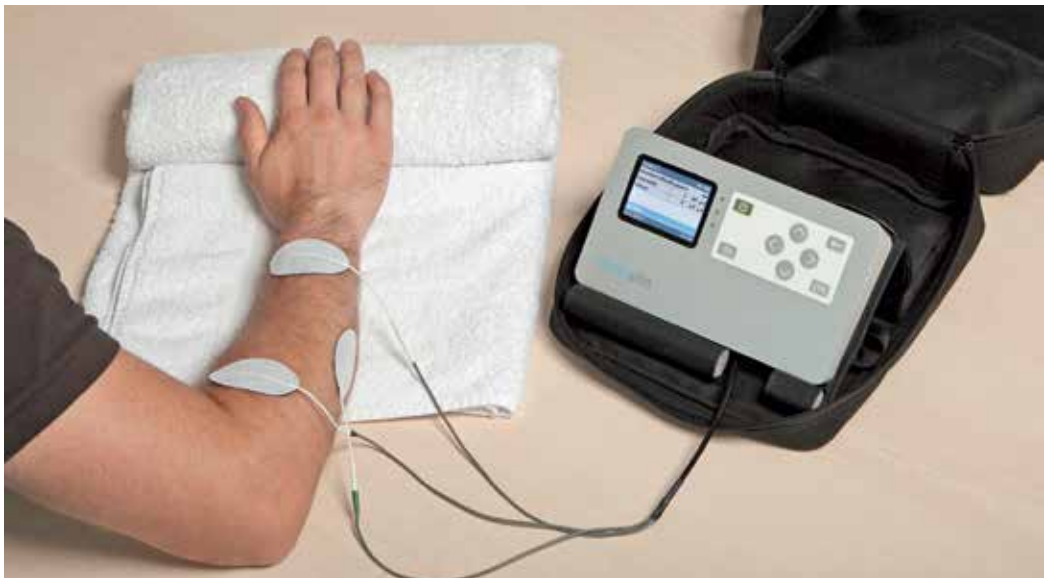
- Product description (variants, application, accessories etc.)
- Product specification (norms/specifications, construction and production diagrams, data sheets, manufacturing specifications, quality assurance measures, designations, instructions for use etc.)
- Product verification (calculations, simulation results, test results, risk management etc.)
- Product validation (manufacturing process, packaging, application process, software etc.)

This documentation effort is a daunting prospect for many developers. It is true that at first glance, it would be easier to deal with the technical tasks only, instead of producing documentation. On closer examination, however, it soon becomes apparent that the regulations also have advantages. There is hardly a programmer who has not regretted that his source code was not properly commented while it was written.



1 **Neurostimulator therapy is intended to restore a patient's mobility after a stroke, for example**

All figures: TG-Group



2 Neurostimulator mentastim has been developed for two different user groups

The development of the neurostimulator ›mentastim‹ (**Figure 1**) shows that the path to successful auditing of a medical device can take a different course. TQ-Systems has developed this therapy device, by means of which nerves and muscles are stimulated electrically, from scratch. The device (**Figure 2**) enables movement sequences to be relearned or learned again after diseases of the central nervous system, a stroke, for example. After being instructed on the use of the device by a doctor or therapist, the patient can use it independently around the home. ›mentastim‹ functions according to the principle of EMG-triggered electrostimulation. In this, an increase in the muscle potential through purely mental movement suggestion is measured in the form of the so-called EMG value. If this value reaches a defined threshold, the device triggers an electrical stimulation. The brain receives positive feedback of successful activation as a result of this stimulation.

This therapy is based on the scientific knowledge that, after damage to brain areas, the central nervous system stores the lost movement patterns in other, undamaged areas, and can therefore learn these again. This effect, which is known as neuroplasticity, is measurably strengthened by EMG-triggered electro stimulation.

One of the greatest challenges today is to bring increasingly complex products on the market within ever shorter periods of time. What is decisive here is making it clear up front as to who contributes to the project, what this contribution is, when it is made, and how it is included into the overall project. Different process models have established themselves as tools for answering these key questions. The palette ranges from classic phase-oriented models such as the waterfall, V, spiral or stage-gate model right up to agile models such as Adaptive Software Development (ASD) or scrum. Every model has its own view of the development process, with corresponding advantages and disadvantages. To find the most suitable model for a project, one needs to know the models. Disabuse yourself immediately of the notion that there is a single model that will proceed from the start to the finish for completing a project successfully! Instead, consider in which phase you need which processes. Combine models or parts of models, define iteration loops and use these to create your own personal process model. This should then be understood, accepted and also lived by all project participants.

Individual process model

A review process was performed at the end of each phase of the development of the neurostimulator. In addition, gates were defined (**Figure 3**) at which a go/no-go decision could be taken. In the case of a no-go for the next phase, a decision for an iteration loop could be taken (spiral model), or the entire project could be cancelled. What initially appears to be drastic could be sensible, because if it is deter- »

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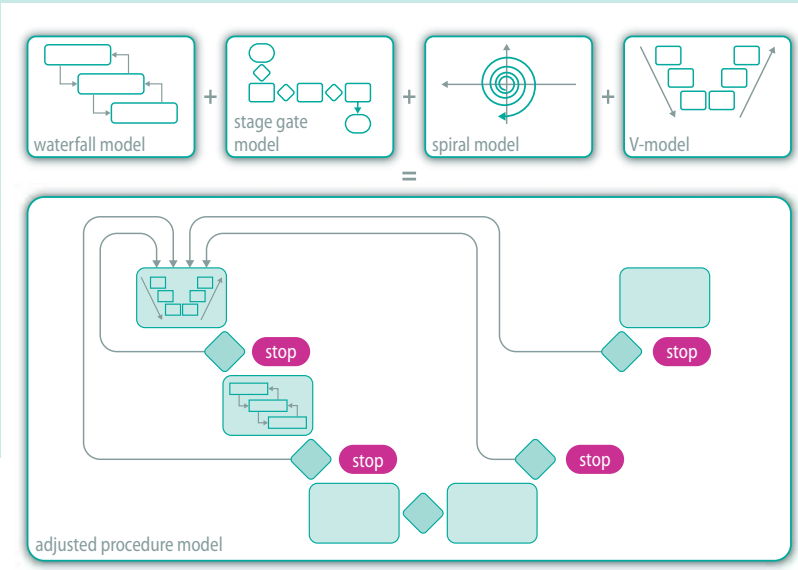

3 An individual model was derived from the combination of four process models. This model was used to successfully develop the neurostimulator

» mined at a gate that continuing with the project is uneconomical a great deal of time and money could be saved.

The early project phase cannot be evaluated highly enough. The cornerstone of the project is laid here. All errors that are committed at the beginning must be corrected at a later stage at a high cost in terms of time and money. Consequently, the first document to be created according to the regulatory specifications – the specification sheet with the intended purpose of the medical device – is decisive for the success of the project. In respect of DIN EN 62366 (Application of Usability Engineering to Medical Devices) as well, it is worthwhile completing pending tasks in an orderly manner. Ultimately, a product should be developed for a specific application, and be used by one (or more) user group(s) in an extremely specific field. The more precisely the following questions can be answered, the better the product will later be accepted by the customer.

- Will the product meet its purpose?
- Can product ideas and features be developed?
- Can decisions be taken in the development process?
- Can risks be identified and avoided?
- Can the product be verified and validated?

Numerous sampling techniques are available for processing product requirements. Examples of these are expert interviews, individual or group interviews, questionnaire techniques or on-site observation. Where preceding models or initial functional prototypes exist, these should be used for the requirements analysis. This could occur within the scope of a comparison or benchmarks, usability tests or focus groups, for example. Regardless of the technique selected, the information generated must be evaluated and weighted. However, it is precisely in the area of interview techniques that experience is required to establish the core of the problem issue. Interviewees often tend to consider possible solutions without being aware of the problem issue. A good example of this is a quote from Henry Ford. He is reputed to have said once: »If I had asked people what they wanted, they would have said faster horses.«

Where is this journey headed?

The neurostimulator is a home-care product, and the main user is consequently the patient. He/she obtains the device from a doctor or therapist on prescription. In addition, the doctor or therapist should be able to adjust the device for the individual patient, and requires the option to be able to save therapy protocols to check the success of the therapy and the settings. As a result, the device must meet the demands of two user groups with differing levels of education, prior knowledge and capabilities – the clinic and the therapist on the one hand, and the patient in a domestic environment on the other. Based on the different requirements, different user profiles have been implemented.

There are additional stakeholders, besides the patients. Co-inhabitants or family members also come into contact with home-care devices. Another example is where nursing staff prepare or clean the device. Here, it is useful to work through different scenarios with regard to usability and risk minimization, and to incorporate experiences gained into the development process at an early stage. If the device is later to be added to the product catalog of the statutory health insurance company, the corresponding requirements and prospects of success should be ascertained. Don't forget the stakeholders in your own organization. Depending on the service provision model, the service division could have certain demands in terms of maintainability or remote diagnosis. If the device is to be introduced into the market in different countries in the long term, it is worth seeking out requirements from Sales and Marketing.

The notified bodies are particularly important stakeholders, as they need to be exposed to the product intensively and need to check all documents for absolute accuracy. The auditing department often induces a kind of testing anxiety in developers and those responsible for the project. This results in a mindset of creating the development documents "for the notified body" and not for the sole purpose of documenting the development process. At the end of the project, the final approval of the medical device then hangs over the team like the sword of Damocles.

All stakeholders considered?

It is better to see the notified body as a development partner. The example of the neurostimulator shows that it can be worthwhile to communicate in good time and openly. In this way, agreement was reached as to a type of cumulative certification. First, a functional prototype was tested and accepted on the basis of fundamental electrical safety. Then, environmental tests (EMV, temperature range, first software components) were performed. The third test comprised the final acceptance of the device, including all mechanical components. The advantages of this procedure are:

- Critical documents such as risk evaluation, application of relevant norms etc. are checked and confirmed in an early phase
- Deviations are detected early and can be remedied before the next check within the scope of the normal development process
- Slim quality control loop
- Unpleasant surprises during the final audit are avoided

The notified bodies have viewed this somewhat uncommon procedure extremely positively. The testers can focus on the relevant areas, and can more easily plan the test into their busy schedules. In short, it is worthwhile to identify the stakeholders and to communicate with them.

As an experienced, certified manufacturer of medical devices, the TQ-Group offers E2MS services during the development and approval of medical devices, and assists in removing obstacles and in bringing the product to the market quicker. The TQ-Group is at your service during the entire product lifecycle – from the product idea and determination of requirements, to planning and development right up to production, maintenance and support for the medical device. This means the medical device manufacturer is free to concentrate on the clinical or medical applications.

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